National Environmental Laboratory **Accreditation** Conference

nelac

ON-SITE ASSESSMENT

PROPOSED

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N O T E: ***Additions*** ***(double-underlined) and*** ~~***deletions***~~ ***(struck through) to the approved standards being considered by the On-site Assessment Committee for vote at the next Annual Meeting are marked as in this note.***

3.0 ON-SITE ASSESSMENT

3.1 INTRODUCTION

The on-site assessment is an integral and requisite part of the NELAC laboratory accreditation program and is one of the primary means of determining a laboratory's capabilities and qualifications. During the on-site assessment, the assessment team collects and evaluates information and makes observations which are used to judge the laboratory's conformance with established accreditation standards.

It is essential that the on-site assessments conducted by all accrediting authorities recognized by the National Environmental Laboratory Accreditation Program be conducted in a uniform, consistent manner.

This section describes the essential elements that must be included in any acceptable on-site assessment and the qualifications and requirements for assessors.

The responsibility for promulgating and enforcing occupational safety and health standards rests with the U.S. Department of Labor. While it is not within the scope of the assessment team to evaluate all health and safety regulations, any obviously unsafe condition(s) observed should be described to the appropriate laboratory official and reported to the accrediting authority. The accreditation on-site assessment is not intended to certify that the laboratory is in compliance with any applicable health and safety regulations.

3.2 ON-SITE ASSESSMENT PERSONNEL

3.2.1 Basic Qualifications

An assessor must be an experienced professional and hold at least a Bachelor’s degree in a scientific discipline or have equivalent experience in environmental laboratory assessment.

Each assessor must satisfactorily complete a training program approved by the accrediting authority responsible for on-site assessments. This program shall include training on the NELAC standards; on how to conduct a laboratory assessment; on the technology and requirements appropriate for each particular field of testing for which they are conducting laboratory on-site assessments; and participation in at least four actual NELAC on-site assessments under the supervision of a qualified assessor. Training in the NELAC standards and on how to conduct a laboratory assessment can be satisfied by successful completion of NELAC Basic Assessor Training. Assessors must take annual refresher/update training as defined in Section 3.2.3. Assessors employed by an accrediting authority (either directly or as a third party) when the accrediting authority is granted NELAP recognition (See Section 6.7) are exempt from the requirement to undergo training with a qualified assessor, provided they have previously conducted four assessments and been judged proficient by the accrediting authority.

All assessors must complete NELAC Basic Assessor Training within two years of becoming an assessor. Assessors must complete the applicable technical training requirements within four years after the NELAC-specified technical training is offered.

Each new candidate assessor must undergo training with a qualified assessor during four or more actual assessments until judged proficient by the accrediting authority.

In addition, the assessors must:

a) Be familiar with the relevant legal regulations, accreditation procedures, and accreditation requirements;

b) Have a thorough knowledge of the relevant assessment methods and assessment documents;

c) Be thoroughly familiar with the various forms of records described in Section 3.5.3 - Records Review;

d) Be thoroughly cognizant of data reporting, analysis, and reduction techniques and procedures;

e) Have a working knowledge and be conversant with the specific tests or types of tests for which the accreditation is sought and, where relevant, with the associated sampling and preservation procedures; and,

f) Be able to communicate effectively, both orally and in writing.

3.2.2 Assessor Qualification

Before an assessor can conduct on-site assessments, an accrediting authority must qualify the individual. Each assessor must sign a statement before conducting an assessment certifying that no conflict of interest exists and provide any supporting information as required by the accrediting authority. Failure to provide this information makes the proposed assessor ineligible to participate in the assessment program.

3.2.3 Training

The National Environmental Laboratory Accreditation Conference (NELAC) specifies the minimum level of education and training for assessors, including refresher/update training. The NELAC also develops standards for training requirements. The assessor training program is implemented by either accrediting authorities, assessor bodies, or other entities. All assessor training programs, must meet the standards defined in the Chapter.

The purpose of the basic assessor training is to familiarize the assessor with the NELAC standards and the skills and techniques associated with the laboratory assessment. ~~The basic assessor training program is defined as follows:~~

~~NELAC Basic Assessor Training~~

~~DAY 1~~

- ~~Basic Laboratory Assessment Techniques and Skills~~

~~DAY 2~~

- ~~NELAC Overview (Chapter 1 NELAC Standards)~~
- ~~Accrediting Authority (Chapter 6)~~
- ~~Accreditation Process (Chapter 4)~~
- ~~Proficiency Testing (Chapter 2)~~

~~DAY 3~~

- ~~Quality Systems (Chapter 5)~~

~~DAY 4~~

- ~~On-site Assessment (Chapter 3)~~

~~DAY 5~~

- ~~Summary~~
- ~~Written Examination~~

~~NOTE: Until such time as the NELAC has developed the training program for laboratory assessors, each accrediting authority shall approve the training for each of its assessors (federal, State and/or third party).~~

When the NELAC has approved the assessor training program standards defined in this section, accrediting authorities, assessor bodies, or other entities may petition for approval of various formal training programs that address laboratory assessment skills which may meet the NELAC standards. It is the intent of this chapter to allow those assessors that produce evidence of successful completion of approved alternative training concerning assessment to be exempt from the analogous NELAC training. The specific training associated with the NELAC standards is required and must be successfully completed. All assessor candidates must pass the written examination.

In addition to the basic NELAC assessor training, each assessor must successfully complete training in at least one technical discipline.

The purpose of the technical training is to ensure consistency of knowledge and techniques among the NELAC assessors. The technical training assumes a level of basic knowledge of the subject and concentrates on the elements of the technology or methods that are key to properly assure laboratory competency to deliver data of known and documented quality. ~~The technical training program consists of the following~~ :

~~NELAC Technical Training for Assessors~~

~~TECHNICAL DISCIPLINES~~

~~1. Microbiology (2.5 days)~~
- ~~S Bacteriology~~
- ~~S Viruses/Parasites~~
- ~~S Microscopic Particulate Analysis (MPA)~~

~~2. Biological (2.5 days)~~
- ~~S Aquatic Toxicity Testing~~
- ~~S Freshwater/Marine/Estuarine Fish~~
- ~~S Freshwater/Marine/Estuarine~~
- ~~S Icthyoplankton~~
- ~~S Macrophytes~~
- ~~S Periphyton~~
- ~~S Phytoplankton~~
- ~~S Zooplankton~~
- ~~S Biomass~~
- ~~S Chlorophyll a (Spectrophotometric and Fluorometric)~~

~~3. Inorganic - Nonmetals/Misc (2.5 days)~~
- ~~S Spectrophotometric~~
- ~~S Titrimetric~~
- ~~S Potentiometric~~
- ~~S Colorimetric~~
- ~~S TOC/TOX~~
- ~~S Residue/Solids~~
- ~~S COD/BOD~~
- ~~S IR~~
- ~~S IC~~

~~4. Inorganic - Metals (2.5 days)~~
- ~~S FAA~~
- ~~S GFAA~~
- ~~S ICP~~
- ~~S ICP/MS~~
- ~~S Sample Preparation (Digestion/TCLP/etc.)~~

~~5. Organics (5 days)~~
- ~~S Sample Preparation~~
- ~~S HPLC~~
- ~~S GC~~
- ~~S GC/MS~~
- ~~S Instrument Software~~

~~6. Asbestos (2.5 days)~~
- ~~S Bulk~~
- ~~S Air~~
- ~~S Water/TEM (Day 1. Assessors not requiring TEM could begin training on second day)~~

~~7. Radiochemistry (2.5 days)~~

~~8. Field Activities (tbd days)~~
- ~~S Source/Ambient Testing (CAA, RCRA, TSCA)~~
- ~~S E.g. Air Source Testing~~
- ~~S Basic Principles of Manual Methods~~
- ~~S Basic Principles of Instrumental Methods~~
- ~~S Soil/Groundwater (SARA, RCRA, TSCA, FIFRA)~~
- ~~S Surface Water (CWA, RCRA, TSCA, FIFRA)~~
- ~~S Drinking Water (SDWA)~~
- ~~S Multi-media (mix of above)~~
- ~~S Biological~~

The purpose for requiring refresher/update training for all assessors is to ensure that the assessors are aware of changes to the standards and/or approved analytical methodology as they occur and to enhance and improve skills associated with assessment. Assessors are expected to maintain proficiency on an on-going basis. Assessors must complete refresher/update training annually. ~~Initially, the refresher/update training is conceptualized as follows:~~

~~NELAC Refresher/Update Training for Assessors~~

~~Day 1~~
- ~~S Changes to the NELAC Standards and the Resulting Checklist Changes~~
- ~~S Technical Changes Associated with Approved Methodology and the Resulting Checklist Changes~~
- ~~S Assessment Skills and Techniques~~
- ~~S Current Developments~~

3.3 FREQUENCY AND TYPES OF ON-SITE ASSESSMENTS

3.3.1 Frequency

The accrediting authority must conduct a comprehensive on-site assessment of each laboratory prior to granting accreditation, except as allowed by interim accreditation (see Section 4.5.1). In addition, an on-site assessment of each accredited laboratory must be completed at least every two years. Assessments for cause are conducted more frequently, at the option of the accrediting authority.

3.3.2 Follow-up On-site Assessments

If directed by an accrediting authority, assessors must conduct follow-up assessments at laboratories where a deficiency was identified by the previous assessment. These assessments may be, but are not necessarily limited to, determining whether a laboratory has corrected its deficiency(ies), or determining the merit of a formal appeal from the laboratory. When deficiencies are of such severity as to possibly warrant the downgrading of a laboratory's accreditation status, any follow-up assessment that is planned or conducted must be completed and reported within thirty (30) calendar days after the receipt of the laboratory's plan of corrective action.

Nothing in this section should be construed as requiring an accrediting authority to reassess a facility prior to taking a regulatory or administrative action affecting the status of the facility's

accreditation. Nothing in this section should be construed as limiting in any way the accrediting authority's ability to revoke or otherwise limit a laboratory's accreditation upon the identification of such deficiencies as to warrant such action.

3.3.3 Changes in Laboratory Capabilities

When a change occurs in a laboratory's ownership, location, key personnel, or major instrumentation, notification of the accrediting authority is required within 30 days (see Section 4.3.2). The accrediting authority must evaluate the significance of a change that might alter or impair the laboratory's capability and quality, and indicate to the laboratory the results of their evaluation in writing. The accrediting authority must retain records to indicate that such an evaluation was conducted.

3.3.4 Announced and Unannounced Visits

The accrediting authority, at its discretion, conducts either unannounced or announced on-site assessments. The accrediting authority is not required to provide advance notice of an assessment.

To the maximum extent practical, accrediting authorities shall, when necessary, work with Federal departments/agencies/contractors to obtain government security clearances for their assessors as far in advance as possible. Federal departments/agencies/contractors shall facilitate expeditious attainment of the necessary clearances.

3.4 PRE-ASSESSMENT PROCEDURES

3.4.1 Assessment Planning

A good assessment begins with planning, which starts before the assessment team visits the laboratory. Planning is the means by which the lead assessor identifies all the required activities to be completed during the assessment process. Planning includes conducting a thorough review of NELAP and/or State records pertaining to the laboratory to be inspected. This saves time because familiarity with the operation, history, and compliance status of the laboratory increases the efficiency and focus of an on-site visit.

Pre-assessment activities include: determining the scope of the assessment; reviewing NELAP/State information; providing advance notification of the assessment to the laboratory, when appropriate; obtaining any security clearances and determining any special safety procedures which may be necessary; coordinating the assessment team; and gathering assessment documents. Section 3.4.5 discusses Confidential Business Information (CBI) issues.

3.4.1.1 Assessment Team

It is encouraged that teams directed by a lead assessor perform assessments. A single assessor knowledgeable in the discipline, methods, and regulations applicable to the laboratories he or she assesses can competently perform some on-site assessments.

The accrediting authority determines the number and expertise of the assessors and support personnel that are required to conduct the on-site assessment based on the type of assessment and the scope of accreditation of the accredited or applicant laboratory.

3.4.1.2 Technical Support Personnel

An assessment team may include technical support personnel approved by the primary accrediting authority as capable of providing assistance to the assessors. These individuals need not be formally qualified by the accrediting authority as assessors (see Section 3.2.2). If not so qualified, these individuals must still meet the requirements of the standards concerning conflicts of interest and professional conduct. Members of the assessment team who provide technical assistance but are not qualified as assessors are not eligible to conduct interviews in the absence of the assessor nor to cite deficiencies.

3.4.2 Scope of the Assessment

The first step in the assessment planning process is deciding the extent of the assessment. The assessment must include both an appraisal of the laboratory's operations and a review of the appropriate records. The assessment for a field of testing must cover the complete scope of accreditation for which the laboratory seeks or maintains accreditation within the specific field of testing as authorized by the accrediting authority.

3.4.2.1 Laboratory Assessments

A laboratory assessment must review the ability of the laboratory to conduct environmental testing. The examination of the systems, processes and procedures of the laboratory should give a general sense of its past and present capabilities to perform work of known and documented quality. During a laboratory assessment, the assessment team must identify a number of samples or a recently completed or on-going project and evaluate to what extent the tests are being conducted according to the NELAC standards.

3.4.2.2 Records Review

The purpose of a records review is to determine whether the testing laboratory has maintained necessary documentation of data, the quality system, and other information to technically substantiate reports previously issued. During a records review, the assessment team conducts an overall assessment of data and compares the data with submitted reports to determine whether the data collected, generated, and reported follow the NELAC standards.

3.4.3 Information Collection and Review

Prior to initiating an on-site assessment, the assessment team shall make determinations as to which laboratory records they wish to review prior to the actual site visit. These records, from the files of the accrediting authority, the national laboratory accreditation database, or the laboratory itself include, but are not limited to:

a) Copies of previous assessment reports and proficiency testing sample results;

b) General laboratory information such as laboratory submitted self-assessment forms, SOPs and Quality ~~Assurance Plan~~Manual(s);

c) Official laboratory communications and associated records with appropriate accrediting authority staff;

d) Available documents from recipients of reports from the laboratory;

e) The laboratory’s application for accreditation;

f) The existing program regulations (federal and state), and ~~special requirements that apply to the areas for which accreditation is sought (i.e. security clearances, radioactive exposure protocols, etc.);~~

g) The most recently approved or in use laboratory methods ~~for the tests~~ for which the laboratory has requested or maintains accreditation~~, and~~.

~~h) The laboratory's Quality Manual.~~

3.4.4 Assessment Documents

Documents necessary for the assessment must be provided to the laboratory management or staff and assembled before the assessment, whenever possible. The lead assessor must obtain copies of all forms required for the assessment, including the appropriate checklist(s). Other types of documents include:

- Assessment Confidentiality Notice;
- Conflict of Interest Form;
- Assessor Credentials;
- Assessment Assignment(s);
- Assessment Notification Letter;
- Attendance Sheet(s) (opening and closing conference); and
- Assessment Appraisal Form.

In addition, the lead assessor must provide information to the laboratory on how to obtain assessment information from the accrediting authority.

3.4.5 Confidential Business Information (CBI) Considerations

During assessments, if assessors come into possession of information claimed as business confidential, the following procedures must be implemented. The EPA regulations for handling confidential business information are detailed in Title 40, Code of Federal Regulations, Part 2, Subpart B and must be followed in NELAP-related matters. Subpart B defines a business confidentiality claim as "a claim or allegation that business information is entitled to confidential treatment for reasons of business confidentiality or a request for a determination that such information is entitled to such treatment."

Consistent with 40 CFR Part 2, NELAC standards must protect Confidential Business Information (CBI) from disclosure. For this information to be adequately protected, NELAP requires certain actions of assessors and the laboratory. The lead assessor must provide a NELAP assessment confidentiality notice to the responsible laboratory official at the beginning of the assessment. This notice informs laboratory officials of their right to claim any portion of the information requested during the assessment data as CBI. NELAP personnel, assessors and other users of said information must have CBI training. The assessors should be familiar with the procedures for asserting a CBI claim and handling information that contain the information claimed as CBI. The lead assessor must take custody of all CBI information before leaving the laboratory, and must maintain them in custody, using all proper procedures and safeguards, until they can be received by the accrediting authority, who must also treat such information as CBI, until an official determination has been made in accordance with federal and State laws.

Certain actions are required of the responsible laboratory official when claiming information as business confidential. The laboratory representative must place on (or attach to) the information at the time it is submitted to the assessor, a cover sheet, stamped or typed legend, or other suitable

form of notice, employing language such as “trade secret”, “proprietary” or “company confidential”. Allegedly confidential portions of otherwise non-confidential information should be clearly identified by the business, and may be submitted separately to facilitate identification and handling by the assessor. CBI may be purged of references to client identity by the responsible laboratory official at the time of removal from the laboratory. However, sample identifiers may not be obscured from the information. If the information claimed as business confidential suggests the need for further action, the information may be forwarded to the appropriate agency that may take further action outside the scope of the accreditation process, to obtain the client’s identity. If the information claimed as business confidential suggests the need for further enforcement action, the accrediting authority is responsible for ensuring that all CBI issues are handled in accordance with NELAC standards.

If a business confidentiality claim is received after the on-site assessment by the accrediting authority, the authority should make such efforts as are administratively practical to associate the late claim with copies of the previously submitted information in its files. However the accrediting authority cannot assure that such efforts will be effective in light of the possibility of prior disclosure or dissemination of the information.

It is not the responsibility of the on-site assessor to make any determination with respect to the validity of a confidential business information claim; this responsibility rests with the accrediting authority. The assessor must maintain custody of CBI-claimed information collected during the assessment until they are delivered to an authorized official of the accrediting authority. CBI-claimed information may be the intellectual property of the laboratory. Therefore, all CBI-claimed information must be held in a secure manner throughout the holding period of assessment records and may not be reproduced or distributed inconsistent with 40 CFR Part 2. If the accrediting authority questions the claim that certain information is CBI, the host laboratory must be contacted and given twenty-one (21) calendar days to:

1) provide justification of their claim to CBI,

2) remove the claim of CBI,

3) resolve the issue in a manner agreeable to both the laboratory and the accrediting authority,

4) engage legal assistance,

5) appeal the action to NELAP, or

6) withdraw their NELAC accreditation application for the field of testing associated with the CBI information.

In no instance shall the accrediting authority declassify CBI-claimed information without notification of the laboratory. If the responsible laboratory official does not consent to declassification of the CBI-claimed information, the laboratory has the option to pursue any or all of the above stated actions.

3.4.6 National Security Considerations

Assessors performing assessments at laboratories owned and/or operated by Federal departments/agencies/contractors must review the need for security clearances, appropriate badging, and/or a security briefing before proceeding with the on-site assessment. The laboratory must inform the assessors in writing of any information, including data, that is controlled for national security reasons and cannot be released to the public.

NELAP assessment teams performing an on-site assessment of a Federal agency may need security clearances, appropriate badging, and/or a security briefing before proceeding with the on-site assessment. Assessors shall be informed in writing of any information that is controlled for national security reasons and cannot be released to the public.

3.5 ASSESSMENT PROCEDURES

3.5.1 Length of Assessment

The length of an on-site assessment depends upon a number of factors such as the scope of~~number of tests for which a laboratory desires~~ accreditation, the number of assessors available, the size of the laboratory, the number of problems encountered during the assessment, and the cooperativeness of the laboratory staff. The accrediting authority must assign an adequate number of assessors to complete the assessment within a reasonable period of time. Assessors must strike a balance between thoroughness and practicality, but in all cases must determine to what extent the laboratories' operations meet NELAC standards.

3.5.2 Opening Conference

Arrival at the facility for routine NELAC assessments occurs during established working hours unless special arrangements are made with the laboratory.

A laboratory's refusal to admit the assessment team for assessment results in an automatic failure of the laboratory to receive accreditation or loss of an existing accreditation by the laboratory, unless there are extenuating circumstances that are accepted and documented by the accreditation authority. The assessment team leader must notify the accrediting authority as soon as possible after refusal of entry.

An opening conference must be conducted and shall address the following topics:

a) the purpose of the assessment;

b) the identification of the assessment team;

c) the tests that will be examined;

d) any pertinent records and operating procedures to be examined during the assessment and the names of the individuals in the laboratory responsible for providing the assessment team with the necessary documentation;

e) the roles and responsibilities of key managers and staff in the laboratory;

f) the procedures related to Confidential Business Information;

g) any special safety procedures that the laboratory may think necessary for the protection of the assessment team while in certain parts of the facility (under no circumstance is an assessment team required or even allowed to sign any waiver of responsibility on the part of the laboratory for injuries incurred by a team member during an inspection to gain access to the facility);

h) the standards that will be used by the assessors in judging the adequacy of the laboratory operation;

i) the confirmation of the tentative time for the exit conference;

j) the presentation of the assessment appraisal form to the responsible laboratory official for submittal to the accrediting authority; and

k) the discussion of any questions the laboratory may have about the assessment process.

3.5.3 On-site Laboratory Records Review and Collection

Assessment team members must review laboratory records for accuracy, completeness and the use of proper methodology. NELAC Chapter 5, Section 5.12 lists the records required for review during the assessment. The assessor must document the required elements of the records review on the NELAC assessment checklists.

The laboratory must mark all confidential information. The lead assessor must handle it as required by appropriate laws and regulations. All other information for all aspects of application, assessment and accreditation of laboratories is considered public information. If the laboratory requests that information is confidential, the information must be treated as confidential until a ruling can be made by the accrediting authority.

3.5.4 Staff Interviews

As an element of the assessment process, the assessment team evaluates the analysis process by requesting that the analyst(s) normally conducting the test(s) give a step-by-step description of exactly what is done and what equipment and supplies are needed to complete the analysis. Any deficiencies shall be noted and discussed with the analyst. The deficiencies must be discussed again in the closing conference.

The assessment team members shall have the authority to conduct interviews with any/all staff**.** Calculations, data transfers, calibration procedures, quality control/assurance practices, adherence to SOPs and report preparation shall be assessed for the complete scope of accreditation with the appropriate analyst(s).

3.5.5 Closing Conference

The assessment team must meet with representative(s) of the laboratory following the assessment for an informal debriefing and discussion of findings. It should be noted that the assessment team in no way limits its ability to identify additional problem areas in the final report should it become necessary. The assessors must describe all deficiencies identified-to-date during the closing conference with the possible exception of any issues of improper and/or potentially illegal actiivity, which may be the subject of further action.

In the event the laboratory disagrees with the findings of the assessor(s), and the team leader adheres to the original findings, the deficiencies with which the laboratory takes exception shall be documented by the team leader and included in the report to the accreditation authority for consideration. The accrediting authority makes a determination as to the validity of the contested elements.

The assessment team must inform the laboratory representative(s) that an assessment report encompassing all relevant information concerning the ability of the applicant laboratory to comply with the accreditation requirements is forthcoming.

3.5.6 Reporting Procedures

The accrediting authority or its authorized third party must present an assessment report to the laboratory within thirty (30) calendar days of the assessment. The laboratory has thirty (30) calendar days from the date of receipt of the report to provide a plan of corrective action to the accrediting authority (see Section 4.1.3). An exception to these deadlines is in those circumstances where a possible enforcement investigation or other action has been initiated.

3.5.7 Assessment Closure

After reviewing the assessment report and any completed corrective action(s) reported by the laboratory, the accrediting authority makes the determination of the accreditation status for a laboratory.

If the deficiencies listed in the initial assessment report are substantial or numerous, additional on-site assessment may be conducted before a final decision for accreditation following the procedures of the accrediting authorities.

3.6 STANDARDS FOR ASSESSMENT

3.6.1 Areas of Assessment

The areas to be evaluated during an on-site assessment to determine the competence of an environmental laboratory shall include:

a) Organization and Management

b) Quality System - Establishment, Assessments, Essential Quality Controls and Data Verification

c) Personnel

d) Physical Facilities - Accommodation and Environment

e) Equipment and Reference Materials

f) Measurement Traceability and Calibration

g) Test Methods and Standard Operating Procedures

h) Sample Handling, Sample Acceptance Policy and Sample Receipt

l) Records

j) Laboratory Report Format and Contents

k) Subcontracting of Analytical Samples

l) Outside Support Services and Supplies

m) Complaints

These areas must be evaluated against the standards detailed in Chapter 5, Quality Systems, Chapter 2, Proficiency Testing and Chapter 4, Accreditation Process of the NELAC Standards and

the appropriate method references. Sufficient detail is provided in Chapter Five (5) and/or the method reference(s) cited to enable accrediting authorities to evaluate laboratories consistently and uniformly.

3.6.2 Assessor's Role

The on-site assessor uses a variety of tools in the assessment process. The experience of the assessor, his/her observations, interviews with laboratory staff, and examination of SOPs, raw data, and the laboratory's documentation all play important roles in the assessment. The accreditation of a particular laboratory depends primarily upon the assessment team's findings. Much of the on-site assessment depends upon the assessor's observations of existing conditions (i.e. observing operations and processes). The recommendation not to accredit a laboratory, or to change a laboratory's accreditation status, must be based on factual information and not upon subjective evaluations. Therefore, it is crucial that the on-site assessor have a clear understanding of the laboratory's procedures and policies and that the assessor document any deficiencies in the assessment report of the on-site assessment. The assessment team must use specific documentation in its reporting of deficiencies.

During the assessment, sufficient information may become available to suspect that a particular person has violated an environmental law or regulation, such as knowingly making a false statement on a report. This information must be carefully documented since further action may be necessary. In the event that evidence of improper and/or potentially illegal activities have or may have occurred, the assessment team must present such information to the accrediting authority for appropriate action(s). These issues, at the discretion of the accrediting authority, may or may not be subjects or issues of the closing conference. However, the assessor must continue to gather the information necessary to complete the accreditation assessment.

3.6.3 Use of Checklists

Standardized checklists must be used for the on-site assessment. The use of checklists does not replace the need for assessor observations and staff interviews, but is another tool that assists in conducting a thorough and efficient assessment. A checklist is not a substitute for assessor training and experience.

3.6.4 Standards of Professional Conduct for Assessors

Professional standards apply to every NELAC assessor, whether a government employee or an employee of a third party organization conducting assessments under an agreement with a NELAP accrediting authority. Assessors that knowingly engage in unprofessional activity may be liable for punitive actions as initiated by the affected accrediting authority.

The Standards for Professional Conduct, as outlined in this section, are based upon 5 CFR 2635, "Standards of Ethical Conduct for Employees of the Executive Branch" and will be followed in NELAP related matters. NELAC assessors shall:

a) have no interest at play other than that of the accrediting authority and NELAC during the entire accreditation process;

b) act impartially and not give preferential treatment to any organization or individual;

c) provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and/or disability;

d) not use their position for private gain;

e) not solicit or accept any gift or other item of monetary value from any laboratory, laboratory representative, or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accrediting authority;

f) not hold financial interests that conflict with the conscientious performance of their duties;

g) not engage in financial transactions using information gained through their positions as assessors to further any private interest;

h) not engage in employment activities (seeking or negotiating for employment) or attempt to arrange contractual agreements with a laboratory that would conflict with their duties and responsibilities as an assessor;

i) not knowingly make unauthorized commitments or promises of any kind purporting to bind the affected accrediting authority and,

j) attempt to avoid any actions that could create even the appearance that they are violating any of the standards of professional conduct outlined in this section.

Assessors are reminded that it is their responsibility to report to the affected accrediting authority any personal issues or activities that constitute a conflict of interest before an assessment occurs. It is up to the affected accrediting authority to determine if the reported issues and activities regarding a specific assessor constitute, or be construed as, a conflict of interest. Appeals of decisions made by accrediting authorities regarding such matters must be directed to the Executive Director of the NELAC, who shall make the final decision as to the merit of such appeals.

3.7 DOCUMENTATION OF ON-SITE ASSESSMENT

3.7.1 Checklists/Records

The checklists used by the assessors during the assessment shall become a part of the permanent file kept by the accrediting authority for each laboratory. The assessor shall specify the laboratory records, documents, equipment, procedures, or staff evaluated and the observations that contributed to the evaluation of "No" for each assessment checklist item. This information must be documented in the comments section or referenced on the checklist. The assessment report must contain sufficient evidence to support all assessment findings and the overall evaluation of the laboratory.

3.7.2 Report Format

The final assessment report shall be written to contain a description of the adequacy of the laboratory as it relates to the assessment standards in Section 3.6.1. Assessment reports must be generated in a narrative format. Documentation of existing conditions at the laboratory must be included in each report to serve as a baseline for future contacts with the facility.

Assessment reports must contain:

a) Identification of the organization assessed (name and address),

b) Date of the assessment,

c) Identification and affiliation of each assessment team member,

d) Identification of participants in the assessment process,

e) Statement of the objective of the assessment,

f) Summary,

g) Assessment observations, findings (deficiencies) and requirements, and,

h) Comments and recommendations.

The Findings and Requirements section must be referenced to the NELAC standards so that both the finding (deficiency) is understood and the specific requirement is outlined. The team leader shall assure that the results within the final assessment report conform to established standards for the evaluated parameters.

The Comments and Recommendations section can be used to convey recommendations aimed at helping the laboratory improve.

3.7.3 Distribution

The accrediting authority shall be recognized as having the responsibility for the distribution of the assessment reports. The assessment team leader shall compile, edit and submit the final report to the accrediting authority.

3.7.4 Release of On-site Assessment Report

On-site assessment reports must be released initially by the accrediting authority only. The reports will be released to the responsible laboratory official(s). The assessment report shall not be released to the National Accreditation Database and the public until findings of the assessment and the corrective actions have been finalized, all Confidential Business Information and information related to national security has been stricken from the report in accordance with prescribed procedures, and the report has been provided to the laboratory (see Section 4.1.3).

In accordance with the Freedom of Information requirements, any documentation adjudged to be proprietary, financial and/or trade information, or relevant to an ongoing enforcement investigation, must be considered exempt from release to the public.

3.7.5 Record Retention Time

Copies of all assessment reports, checklists, and laboratory responses must be retained by the accrediting authority for a period of at least five (5) years, or longer if required by specific State or Federal regulations (see Sections 4.3.3 & 5.12.2(b)).